# EXHIBIT D

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| MUTUAL PHARMACEUTICAL COMPANY, INC.,<br><br>Plaintiff,<br><br>v.<br><br>PFIZER INC.,<br><br>Defendant. | Case No. 1:03CV01116 (RMU) |

**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANT PFIZER INC.'S MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION**

Defendant Pfizer Inc. ("Pfizer"), through its undersigned counsel, respectfully submits this memorandum of points and authorities in support of its motion, pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, to dismiss Mutual Pharmaceutical Company, Inc.'s ("Mutual") complaint for declaratory judgment ("Complaint").

## I. INTRODUCTION

Mutual's action for declaratory judgment of non-infringement should be dismissed. Mutual cannot have an objectively reasonable apprehension of being sued by Pfizer for patent infringement, and there is no "controversy" as described by Mutual in its Complaint. Rather, Mutual is using the pretext of a declaratory judgment action against Pfizer to prematurely commence the 180-day period of exclusivity in the generic market to which Mutual's competitor, Teva, is statutorily entitled. Neither Pfizer nor this Court should be put to the significant trouble and expense of this unnecessary patent litigation.

Pfizer manufactures and markets Accupril® brand *quinapril hydrochloride*, a medication currently approved for treatment of hypertension and congestive heart failure. Accupril® is covered by several United States patents, including U.S. Patent No. 4,743,450 (the "'450 patent"). Mutual seeks to market a generic equivalent of Pfizer's Accupril® tablets and has filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") seeking approval to do so. In filing its ANDA, Mutual notified Pfizer that it seeks to market generic *quinapril hydrochloride* before the expiration of the '450 patent and that Mutual's manufacture, use and sale of its quinapril hydrochloride tablets will not infringe the '450 patent.

A party seeking a declaration of non-infringement must demonstrate that there is sufficient immediacy in its claim to warrant a court's rendering what would otherwise be an impermissible advisory opinion, and that there is a reasonable apprehension that it will face an infringement suit if it commences or continues the activity in question. There is no immediacy in Mutual's claim. In addition, Mutual has failed to plead any facts in the Complaint supporting its allegation that there is a reasonable apprehension of suit, and, in fact, has admitted facts that demonstrate the lack of an objectively reasonable apprehension. Accordingly, this action should be dismissed for lack of subject matter jurisdiction.

Mutual admits that its purpose in bringing this declaratory judgment action against Pfizer is to trigger the 180-day period of generic market exclusivity for *quinapril hydrochloride* to which Mutual's competitor, non-party Teva, is entitled. Because Teva was the first generic manufacturer to file an ANDA for *quinapril hydrochloride*, it is entitled, by statute, to temporary generic market exclusivity. Litigation between Pfizer and Teva relating to Teva's ANDA is currently pending, but Mutual hopes to obtain a result in the present suit that would start Teva's

exclusivity period before any decision in the Teva litigation. That way, Teva would be deprived of the opportunity to base the marketing of its products on events in its litigation with Pfizer. Mutual's interest in spoiling Teva's statutory benefit for competitive purposes satisfies neither of the requirements of declaratory judgment jurisdiction in an action against Pfizer, and undermines the Congressional intent set forth in the Hatch-Waxman Act.

## II. FACTS

### A. The Parties

Defendant Pfizer is a research-based global pharmaceutical company. (Declaration of Patrick Holmes ("Holmes Decl.") ¶ 2.) Pfizer is an innovator and leader in the pharmaceuticals industry and each year invests heavily in research and product development to discover, develop, and bring to market new products that address major unmet health care needs. (Holmes Decl. ¶ 3.)

Mutual manufactures and sells generic pharmaceutical products. As a generic manufacturer, Mutual relies on the innovator's safety and efficacy data, and other relevant material, when seeking approval to market a bioequivalent drug.

### B. Accupril®

Accupril® is the brand name for Pfizer's formulation of *quinapril hydrochloride*, which is presently approved by the FDA for the treatment of hypertension and for the management of heart failure. (Holmes Decl. ¶ 4.) Accupril® has been on the market in the United States since 1991. (Holmes Decl. ¶ 5.)

Pursuant to 21 U.S.C. § 355(b)(1), Pfizer filed with the FDA the patent numbers and expiration dates for each patent covering Accupril® tablets or a method of use for Zoloft® tablets. 21 U.S.C. § 355(b)(1), (c)(2)(2002). The FDA publishes this information in a list of

pioneer medicines and their related patent information in *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." 21 U.S.C. §355(j)(7)(A). Among the patents listed in the Orange Book for Accupril® is the '450 patent, which expires on February 24, 2007.

### C. Mutual Seeks Approval To Market Generic *Quinapril hydrochloride* Tablets

#### 1. Abbreviated New Drug Applications

Since enactment in 1984 of the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), generic pharmaceutical manufacturers have been permitted to seek expedited approval to market generic drug products by submitting ANDAs. See 21 U.S.C. § 355(j); 21 C.F.R. §314.94. An ANDA relies on the FDA's previous determination, made after review of the pioneer company's exhaustive New Drug Application ("NDA"), that the drug product is safe and effective for the uses for which it has been approved. 21 U.S.C. § 355(j)(2). The generic applicant is required to demonstrate that the product for which it seeks approval is bioequivalent to the product already approved by the FDA. Id.

When a party files an ANDA seeking approval to market a generic version of a drug product covered by one or more patents listed in the Orange Book, the ANDA must include a certification with respect to every listed patent. 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). For each patent claiming the listed drug or use of the listed drug, the applicant must make one of four certifications: (I) that no patent information on the product has been submitted to the FDA; (II) that the patent listed has expired; (III) that the patent will expire on a stated date; or (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA applicant seeks approval. 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(IV). Where a patent listed in the Orange Book is a method-of-use patent

claiming a use different from that for which the ANDA seeks approval, the ANDA filer has the additional option of filing a "section 8" certification. 21 U.S.C. § 355(j)(2)(A)(viii). Pfizer's '450 patent is not a method-of-use patent. Therefore, a section 8 certification with respect to the '450 patent not an option for an ANDA filer. Id.

According to the statutory provisions set forth above, when there are unexpired patents in the Orange Book that claim the ANDA applicant's product or use for such product, and a section 8 certification is not an option, then the applicant must make either a paragraph III or IV certification. 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(IV). If an applicant makes a paragraph III certification to a patent, the FDA cannot approve the ANDA until the date in the certification, i.e., the date on which that patent expires. 21 U.S.C. § 355(j)(5)(B)(ii). If the ANDA applicant makes paragraph III certifications to multiple patents, the approval date is the expiration date of the latest-expiring patent. 21 U.S.C. § 355(j)(5)(B)(ii).

An applicant that makes a paragraph IV certification must also provide the pioneer company and the patent owner (often the same party) with a notice containing a detailed statement of the factual and legal bases for the applicant's assertion that its product will not infringe, or that the patent is invalid. 21 U.S.C. § 355(j)(2)(B). If the pioneer company sues the applicant for patent infringement within 45 days of receipt of that notice, then the FDA cannot approve the ANDA until the earlier of 30 months from the date of notice of the Paragraph IV Certification or a court decision finding the patent invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii).

The first generic applicant to file an ANDA containing a paragraph IV certification, also known as a "first filer," is eligible for a 180-day exclusivity period during which it is entitled to have the only generic version of the drug at issue on the market. 21 U.S.C. § 355(j)(5)(B)(iv).

The 180-day exclusivity period is calculated from the earlier of either (i) the date of the first commercial marketing of the generic drug by the "first filer," or (ii) the date of a court decision declaring the patent at issue invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv)(I), (II). A subsequent ANDA applicant must wait until the "first filer's" 180 days have lapsed before the FDA can approve its ANDA.

**2. Teva is the first to file a *quinapril hydrochloride* ANDA**

On January 15, 1999, Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA seeking approval to market generic *quinapril hydrochloride* tablets. (Declaration of Jeffrey N. Myers ("Myers Decl.") Ex. A at 2.) Shortly thereafter, Teva notified Warner-Lambert Company ("WLC"), Pfizer's predecessor in interest, that it had filed this ANDA. (Myers Decl. ¶ 2.) The notice stated that Teva's ANDA contained a paragraph IV certification with respect to the '450 patent asserting that the '450 patent is invalid. (Myers Decl. ¶ 3.) Within 45 days of receipt of Teva's notification, WLC brought an action against Teva for infringement of the '450 patent ("Teva Case"). (Myers Decl. ¶ 4.) That action is pending. (Id.) Currently, summary judgment motions have been served by both Teva and Pfizer, but briefing has not been completed. As the "first filer" of a *quinapril hydrochloride* ANDA, Teva is entitled to a 180-day period of generic exclusivity from the earlier of either (i) the date it first commercially markets generic *quinapril hydrochloride*, or (ii) the date of a court decision declaring the '450 patent invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv)(I), (II). Teva's ANDA was tentatively approved by the FDA on February 8, 2002, and final approval was granted on May 30, 2003.

On June 13, 2002, the court in the Teva Case issued an opinion on five claim construction issues related to the '450 patent claims. (Myers Decl. Ex A.) Among other things, the court

construed the claims of the '450 patent to include only formulations containing carbonate, and to exclude formulations containing only bicarbonate. (Id.)

**3. Mutual's ANDA**

According to Mutual's Complaint, Mutual filed an ANDA with the FDA to market *quinapril hydrochloride* products. (Complaint ¶ 6.) Mutual made a paragraph IV certification with respect to the '450 patent, certifying that the patent will not be infringed by the manufacture, use or sale of the generic products for which it filed an ANDA. (Myers Decl. Ex. B.) On March 31, 2003, Mutual sent Pfizer a letter notifying Pfizer pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) that it had filed an ANDA containing a paragraph IV certification with respect to the '450 patent. (Id.) Mutual's notice details the legal and factual bases why Mutual contends its generic *quinapril hydrochloride* products do not infringe the '450 patent. (Id.) Pfizer did not bring suit within 45 days of receiving the notice. (Myers Decl. 7.)

In its notice, Mutual contends, inter alia, that its generic products do not literally infringe any of the pharmaceutical claims in the '450 patent because Mutual's formulation contains bicarbonate, not carbonate. (Myers Decl. Ex. B at 6.) Because the court in the Teva Case construed the claims of the '450 patent to only include formulations containing carbonate, and to exclude formulations containing only bicarbonate, the court's claim construction, according to Mutual, should be "binding under collateral estoppel, and Pfizer cannot re-litigate that claim construction." (Id.) Mutual further argues that the doctrine of prosecution history estoppel precludes Pfizer from asserting that the claims in the '450 patent cover Mutual's formulation, and thus Mutual's generic products do not infringe any claims in the '450 patent under the doctrine of equivalents. (Myers Decl. Ex. B at 6-8.)

Mutual concludes in its notice that there should be "no doubt whatsoever" that Mutual's generic *quinapril hydrochloride* tablets do not infringe the '450 patent:

> Thus, no reasonable basis exists upon which Pfizer can institute suit against Mutual for the filing of the [ANDA] . . . Under these circumstances, Mutual would view the filing of litigation against it by Pfizer to be a clear violation of Rule 11 of the Federal Rules of Civil Procedure. Additionally, such a suit would render this case "exceptional" under 35 U.S.C. § 285, warranting the award of attorneys' fees to Mutual.

(Myers Decl. Ex. B at 9.) Mutual states that should Pfizer sue Mutual for infringement of the '450 patent,

> Mutual will not only aggressively defend against any baseless lawsuit filed by Pfizer, Mutual will also seek all appropriate remedies to redress what could only be viewed as a fraudulent misuse of Pfizer's patent, resulting in antitrust liability, harming Mutual and the patients who currently use Accupril® tablets.

(Id.)

## III. ARGUMENT

### A. MUTUAL'S COMPLAINT FOR DECLARATORY JUDGMENT MUST BE DISMISSED FOR LACK OF SUBJECT MATTER JURISDICTION

The Declaratory Judgment Act permits a court to declare the rights and other legal relations of an interested party seeking such declaration only in "a case of actual controversy." 28 U.S.C. § 2201. "The requirements for a justiciable case or controversy are no less strict in a declaratory judgment proceeding than in any other type of suit." Alabama State Fed. of Labor v. McAdory, 325 U.S. 450, 461 (1945) (citations omitted). Thus, the declaratory judgment procedure "may not be made the medium for securing an advisory opinion in a controversy which has not arisen." Coffman v. Breeze Corps., Inc., 323 U.S. 316, 324 (1945) (citations omitted). Rather, the issue must be "actual and adversary." Id. (citations omitted).

The U.S. Court of Appeals for the Federal Circuit, which hears all appeals in patent infringement cases, has held that to maintain a declaratory judgment action for patent invalidity or non-infringement, a plaintiff must satisfy two requirements: (1) the alleged infringer must be engaged in an activity directed toward making, selling, or using subject to an infringement charge, or be making meaningful preparation for such activity; and (2) the party bringing the declaratory judgment action must have a reasonable apprehension of suit. Lang v. Pacific Marine & Supply Co., Ltd., 895 F.2d 761, 764 (Fed. Cir. 1990). To satisfy the reasonable apprehension element, "the defendant in such an action must have engaged in conduct that created on the part of the declaratory judgment plaintiff a reasonable apprehension that it will face an infringement suit if it commences or continues the activity in question." Jervis B. Webb Co. v. Southern Sys., Inc., 742 F.2d 1388, 1398 (Fed. Cir. 1984) (citations omitted). The "reasonable apprehension" prong requires the court to examine the conduct of both the plaintiff and the defendant. Lang, 895 F.2d at 764. The test is objective; purely subjective impressions of the plaintiff are insufficient to satisfy the requirement. Indium Corp. of Am. v. Semi-Alloys, Inc., 781 F.2d 879, 883 (Fed. Cir. 1985).

Moreover, a declaratory judgment action for infringement or non-infringement will stand only if the allegations support a finding of "immediate and real controversy." Lang, 895 F.2d at 764. Without sufficient immediacy and reality, a declaratory judgment action fails to meet the actual controversy requirement of the Declaratory Judgment Act. Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520, 1527 (Fed. Cir. 1992).

Mutual's purpose in bringing this suit is to trigger the period of generic market exclusivity to which Mutual's competitor, non-party Teva, is entitled by statute. To accomplish this purpose, it has manufactured a controversy with Pfizer that is not borne out by the facts.

Mutual has failed to demonstrate an objective basis for its alleged reasonable apprehension of suit and Mutual's allegedly infringing activities are too remote to meet the immediate and real controversy test.

**1. Mutual Has Alleged No Facts To Support Its Claim of Reasonable Apprehension, And the Evidence Demonstrates That Mutual Can Have No Reasonable Apprehension of Suit**

Reasonable apprehension must be proved by objective evidence of the conduct of the defendant-patentee: "A purely subjective apprehension of an infringement suit is insufficient to satisfy the actual controversy requirement." Indium Corp., 781 F.2d at 883. For an actual controversy to exist, "more is required than the existence of an adversely held patent." BP Chemicals Ltd v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993). "The declaratory judgment plaintiff carries the burden of proving the existence of facts underlying his allegations of the existence of an actual controversy." Indium Corp., 781 F.2d at 883 (citation omitted). Where a patentee has never sued or threatened to sue the supposed infringer for infringement of the patents at issue, the Federal Circuit has held that no reasonable apprehension exists. Id.

Mutual has alleged no facts supporting its alleged reasonable apprehension of suit by Pfizer, other than that "Pfizer has never communicated to Mutual its intention not to bring a lawsuit against Mutual." (Complaint ¶ 11.) Mutual's conclusory allegation that it "is under a reasonable apprehension of suit by Pfizer for infringement of the '450 patent," (Complaint ¶ 14), is unsupported by any factual allegation. See Mallinckrodt Medical, Inc. v. Sonus Pharmaceuticals, Inc., 989 F. Supp. 265, 269-70 (D.D.C. 1998) (dismissing claims for lack of subject matter jurisdiction after finding no actual case or controversy where party failed to allege threats or other activity which could potentially create reasonable apprehension of suit).

In fact, the objective evidence, much of which was supplied by Mutual in its notice to Pfizer, demonstrates that Mutual cannot have an objectively reasonable apprehension of suit for

infringement of the '450 patent. To begin with, in its paragraph IV certification, Mutual represented to the FDA that Mutual's generic Accupril® tablets do not infringe Pfizer's '450 patent. Mutual repeated this claim to Pfizer in its notice, which sets forth in detail the legal and factual bases why "there should be no doubt whatsoever" that its proposed generic will not infringe the '450 patent. (Myers Decl. Ex. B at 6.)

In its notice, Mutual relies heavily on the claim construction of the '450 patent in the Teva Case, which Mutual asserts is binding by collateral estoppel for these purposes. (Myers Decl. Ex. B.) Mutual asserts that, according to that claim construction, Mutual's formulation does not infringe the '450 patent. (Myers Decl. Ex B at 6.) Specifically, the claims have already been construed to include only formulations of *quinapril hydrochloride* tablets that contain carbonate, and to exclude formulations that contain only bicarbonate. (Id.) According to Mutual's notice, its formulation contains only bicarbonate. (Id.) Therefore, because (1) the claims were construed essentially in Mutual's favor before Mutual even filed its ANDA, (2) Mutual considers that construction to be binding in this case, and (3) under that claim construction, Mutual insists that its formulation does not infringe, Mutual cannot possibly be under a reasonable apprehension that Pfizer will sue.

Mutual does not allege in the Complaint that Pfizer rejects Mutual's position, and the evidence is to the contrary. Had Pfizer brought an infringement action against Mutual within the 45 days after Pfizer's receipt of Mutual's notice, the ANDA rules would have automatically postponed the approval of Mutual's ANDA by at least 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). Mutual concedes that Pfizer did not bring such an action, (Complaint ¶ 11), and Mutual has presented numerous reasons why Pfizer should *not* bring such an action.

Mutual is so confident of its position, in fact, that it informed Pfizer that any lawsuit against Mutual for infringement of the '450 Patent would be "baseless litigation." (Myers Decl. Ex. B at 9.) Moreover, Mutual threatened that, should Pfizer take the "precarious route" of filing such a lawsuit against Mutual, Pfizer will be subject to Federal Rule 11 sanctions, attorneys fees under 35 U.S.C. § 285, and will attract "great interest" from the Federal Trade Commission. (Id.) Mutual has concluded that it would be preposterous, and in fact unethical, for Pfizer to sue; ironically, Mutual has now sued Pfizer in full view of the same facts. Mutual cannot now do an about-face and, solely for purposes of the instant declaratory judgment action, also claim reasonable apprehension of suit. See, e.g., C&E Services, Inc. v. District of Columbia Water and Sewer Auth'y, 310 F.3d 197, 201 (D.C. Cir. 2002) (stating that it is "well-established" that the Declaratory Judgment Act "is not an independent source of federal jurisdiction. Rather, the availability of declaratory relief presupposes the existence of a judicially remediable right.") (citations omitted).

That Pfizer did not sue Mutual within the statutorily prescribed 45 days of receipt of Mutual's notice also undermines a claim of reasonable apprehension. Had Pfizer sued within the 45 days, an automatic stay would have prevented the FDA from approving Mutual's ANDA for 30 months. Because Pfizer did not sue within the 45 days, there is no 30 month stay and the FDA can approve Mutual's ANDA now, subject only to Teva's 180-day generic market exclusivity. Therefore, Pfizer's incentive to sue Mutual for infringement based on its ANDA filing has disappeared. Because Mutual has failed to show a reasonable apprehension of suit by Pfizer, its Complaint must be dismissed. Indium Corp., 781 F.2d at 883; BP Chemicals Ltd, 4 F.3d at 980.

**2. Mutual Has Failed to Allege an Immediate and Real Controversy**

A declaratory judgment action for patent infringement must be supported by a sufficient allegation of immediacy and reality. Lang, 895 F.2d at 764. To determine whether the controversy is "sufficiently real and substantial," a court "looks to the accused infringer's conduct." Id. There is no sufficiently immediate controversy over which a court may exercise jurisdiction where the alleged infringer's device is far from potential FDA approval and the alleged infringer is "prohibited by FDA regulations" from performing acts that might constitute infringement. Telectronics, 982 F.2d at 1527. Where the declaratory plaintiff is the potential infringer, it must allege that it would and could begin production immediately. Sweetheart Plastics, Inc. v. Illinois Tool Works, Inc., 439 F.2d 871, 875 (1st Cir. 1971); Bristol-Myers Squibb Co. v. IVAX Corp., 77 F. Supp.2d 606, 618-19 (D.N.J. 2000).

If potential infringement depends on future FDA approval, therefore, sufficient immediacy is not established. Bristol-Myers, 77 F. Supp.2d at 618-19. In NeoRX Corp. v. Immunomedics, Inc., 877 F. Supp. 202, 214 (D.N.J. 1994), the court, relying on the reasoning of the Federal Circuit in Telectronics, denied plaintiff's motion for declaratory judgment because approval of the allegedly infringing drug was not imminent. The court held that, like the product in Telectronics, the drug at issue in NeoRX might never be approved, and, even if approved, might not be approved in its current state. Id.

Mutual makes only one allegation that can possibly be construed as relating to immediacy. In paragraph 12 of its Complaint, Mutual alleges that "On information and belief, the FDA's review of Mutual's ANDA No. 76-651 will be completed in the near future." This lone statement is an insufficient allegation of immediacy for purposes of declaratory judgment. First, the completion of FDA review does not mean FDA approval; indeed, the FDA might reject

Mutual's application for any number of reasons. Second, "near future" is an intentionally nebulous, subjective term, demonstrating nothing. Mutual fails to specify what facts underlie its allegation that FDA review will be completed in the near future and, as pled, cannot qualify for immediacy under the declaratory judgment standard for patent cases. For example, in Lang, the Federal Circuit affirmed dismissal of a declaratory action on the grounds that the controversy was not sufficiently immediate where the allegedly infringing ship's hull was at least nine months from completion. Lang, 895 F.2d at 764. Similarly, the Federal Circuit held that there is no sufficiently immediate controversy over which a court may exercise jurisdiction where the alleged infringer's device is years from potential FDA approval. Telectronics, 982 F.2d at 1527.

Mutual filed its ANDA less than six months ago. Mutual does not allege that the FDA is poised to grant approval, and there is no guarantee that the FDA will ever approve Mutual's ANDA. Mutual also does not allege that it is prepared to begin to produce and market its product immediately. NeoRX Corp., 877 F. Supp. at 214. Mutual's potential infringement of the '450 patent is therefore "too remote and unduly speculative" to support a finding of sufficient immediacy. Swedlow, Inc. v. Rohm & Haas Co., 455 F.2d 884, 886 (9th Cir. 1972). A declaration by this Court of Mutual's rights at this stage would constitute an impermissible advisory opinion. Bristol-Myers, 77 F.Supp.2d at 619.

### B. THIS ACTION SHOULD BE DISMISSED BECAUSE MUTUAL'S PURPOSE IN BRINGING IT CANNOT SUPPORT DECLARATORY JUDGMENT JURISDICTION

Teva filed the first ANDA with a paragraph IV certification with respect to Pfizer's Accupril® medication. Teva is now entitled to 180 days of exclusivity in the generic market – a period intended by Congress as a reward for being the "first filer" – which will commence on either (i) the date Teva first commercially markets its generic product, or (ii) the date of a court decision declaring Pfizer's '450 patent invalid or not infringed, whichever is earlier. 21 U.S.C. §

355(j)(5)(B)(iv)(I), (II). Although the Teva Case is pending, Mutual now hopes to obtain a "court decision" of non-infringement of the '450 patent, an event that would trigger Teva's exclusivity period before any decision in the Teva Case. To achieve its competitive purpose, Mutual would put this Court and Pfizer to the significant expense and trouble of a premature, unnecessary patent litigation. This purpose satisfies neither of the requirements of declaratory judgment jurisdiction. Lang, 895 F.2d at 764.

Although promoting generic competition generally may be an aim of the Hatch-Waxman Act, Congress sought to achieve that purpose through the mechanisms explicitly described in the statute. Specifically, Congress intended to confer the 180-day exclusivity benefit on generic manufacturers like Teva which take the significant risk of being the first to challenge an innovator company's patent, in this case the '450 patent. If Mutual is permitted to proceed in this case, then Mutual will have undermined both the Declaratory Judgment Act and the Hatch-Waxman Act.

The Hatch-Waxman Act did not amend the Declaratory Judgment Act, and the declaratory judgment procedure does not exist to facilitate competitive maneuvering. It is appropriate only where a case of actual controversy exists between the parties. 28 U.S.C. § 2201. This action has nothing to do with any immediate controversy that Mutual has with Pfizer. As discussed supra Part III(A), Mutual has failed to demonstrate that such a controversy exists. Although an ANDA filer might not "have any obligation to avoid triggering litigation that would advantage [itself] by starting the 180-day exclusivity period" of the first-filing generic manufacturer, Minnesota Mining & Mfg. Co. v. Barr Labs., Inc., 289 F.3d 775, 781 (Fed. Cir. 2002), no court has ever recognized the triggering of another generic manufacturer's exclusivity period as a sufficient basis, alone, to support declaratory judgment jurisdiction. This Court

should decline Mutual's invitation to be the first. Mutual should not be permitted to abuse the declaratory judgment procedure by dragging this Court and Pfizer into an expensive and unnecessary lawsuit, the only purpose of which is to obtain a tactical advantage over a non-party.

Given Mutual's insistence that an action by Pfizer against Mutual for infringement of the '450 patent would be meritless, and Mutual's admission that its purpose in bringing the instant declaratory judgment action against Pfizer is simply to trigger the 180-day period of market exclusivity to which Mutual's competitor, non-party Teva, is entitled, Mutual cannot establish declaratory judgment jurisdiction.

## IV. CONCLUSION

For the foregoing reasons, this Court should (1) dismiss Mutual's declaratory judgment action with an Order specifying that the dismissal is based on this Court's lack of subject matter jurisdiction and not on the merits of Mutual's claim, (2) award Pfizer its costs and reasonable attorneys' fees for having to respond to Mutual's Complaint, (3) grant such other and further relief as this Court may deem just and proper.

Dated: July 8, 2003
Washington, DC

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of July, 2003, true and correct copies of Pfizer's Motion to Dismiss for Lack of Subject Matter Jurisdiction, Pfizer's Statement of Points and Authorities in Support thereof, the Declarations of Patrick Holmes and Jeffrey N. Myers, and the accompanying proposed Order were sent by facsimile and Federal Express to:

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